Health IT +
Patient Safety

智慧醫療發展與病安風險

Smart IT on the Patient Safety of Health Care

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AUG 11 2023

HIT to Safety

AGENDA

- 醫療資訊科技(HIT)與病人安全風險
- HIT-管理策略與安全認證
- HIT-病安事件之通報系統
- HIT-醫院評鑑相關法規

HIT and Patient-Related Harmful Incidents

MENU | B | METRO | SPORTS | BUSINESS | OPINION | HEALTH | RHODE ISLAND | SPOTLIGHT | LIFESTYLE | POLITICS | ARTS | GLOBE MAGAZINE | CORONAVIRUS

Hazards tied to medical records rush

Subsidies given for computerizing, but no reporting required when errors cause harm

By Christopher Rowland Globe Staff, July 20, 2014, 12:00 a.m.

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FIERCE Biotech | Research | Biotech | Medtech | CRO | Special Reports | Trending Topics | Podcasts

MEDTECH

Philips updates latest ventilator recall following report of patient death, 4 injuries

By Andrea Park • Jun 6, 2022 11:13am

Philips | Class I recall | ventilator | device safety

U.S.News | NEWS » | News | Best Countries | Best States | Healthiest Communities | Opinion | Elections | The Racial Divide | Photos | Events | The Report

Home / News / 'Countless' Patients Harmed B...

'Countless' Patients Harmed By Wrong or Delayed Diagnoses

Evidence is incomplete, but still shows most patients will be impacted by the problem at some point in their lives.

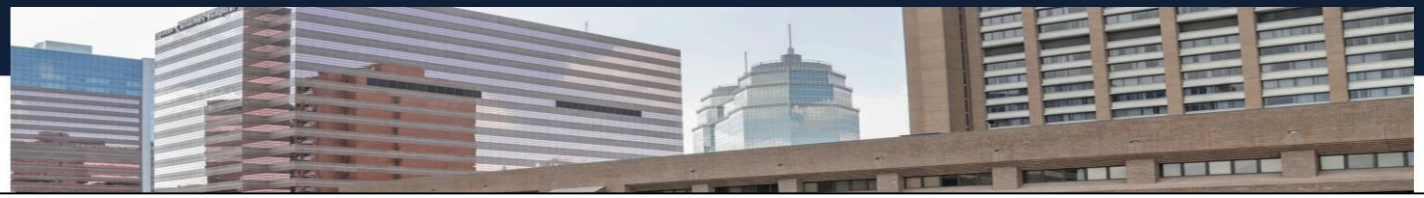
By Steve Sternberg | Sept. 22, 2015, at 11:25 a.m.

NEWS | Ransomware attack delays patient care at hospitals across the U.S. | SHARE & SAVE

SECURITY

Ransomware attack delays patient care at hospitals across the U.S.

CHI Memorial Hospital in Tennessee, some St. Luke's hospitals in Texas and Virginia Mason Franciscan Health in Seattle all have announced they were affected.



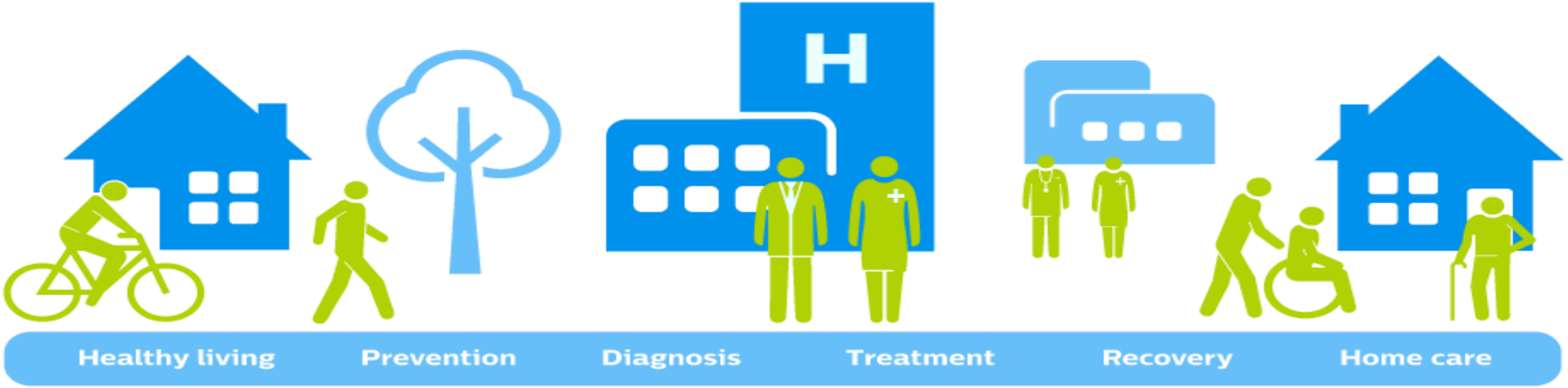
Oct. 7, 2022,

One of the largest hospital chains in the U.S. [**Common Spirit Health**] was hit with a suspected ***ransomware cyberattack*** this week, leading to **delayed surgeries, hold ups in patient care and rescheduled doctor appointments** across the country.

醫療科技與病人安全風險

Healthcare Information Technology and Patient Safety

醫療資訊科技(HIT)對醫療照護影響的重要性



將從**診所(Clinic)**延伸到**患者(Patient)**終端醫療照護

了解病患在**自然環境下(In the wild)行為**和**生理機能**

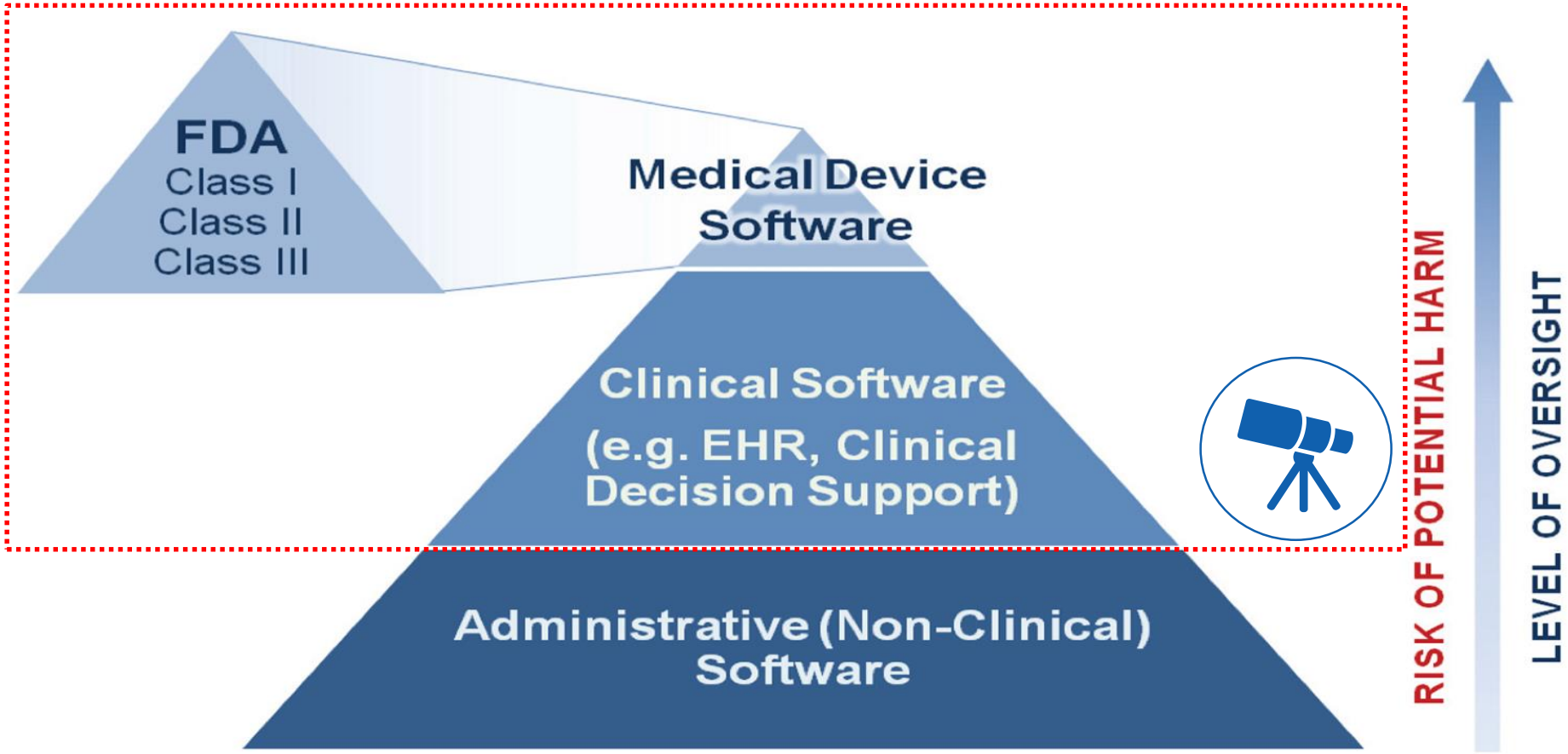
強調在**早期/影響較小(early /smaller)**，進行疾病**介入預防(prevention)**

智慧醫療照護(Smart health care) 利用與串接大量的**計算能力(Computing power)**、**感知器(Sensors)**、**串接功能(Connectivity)**、**系統軟體(Software)**

HIT to Safety

醫療資訊科技(HIT)的風險與監管

HIT與病人安全監督與管理架構，利用現有的病人安全、品質管理流程、資訊系統標準，反映基於風險的共同責任

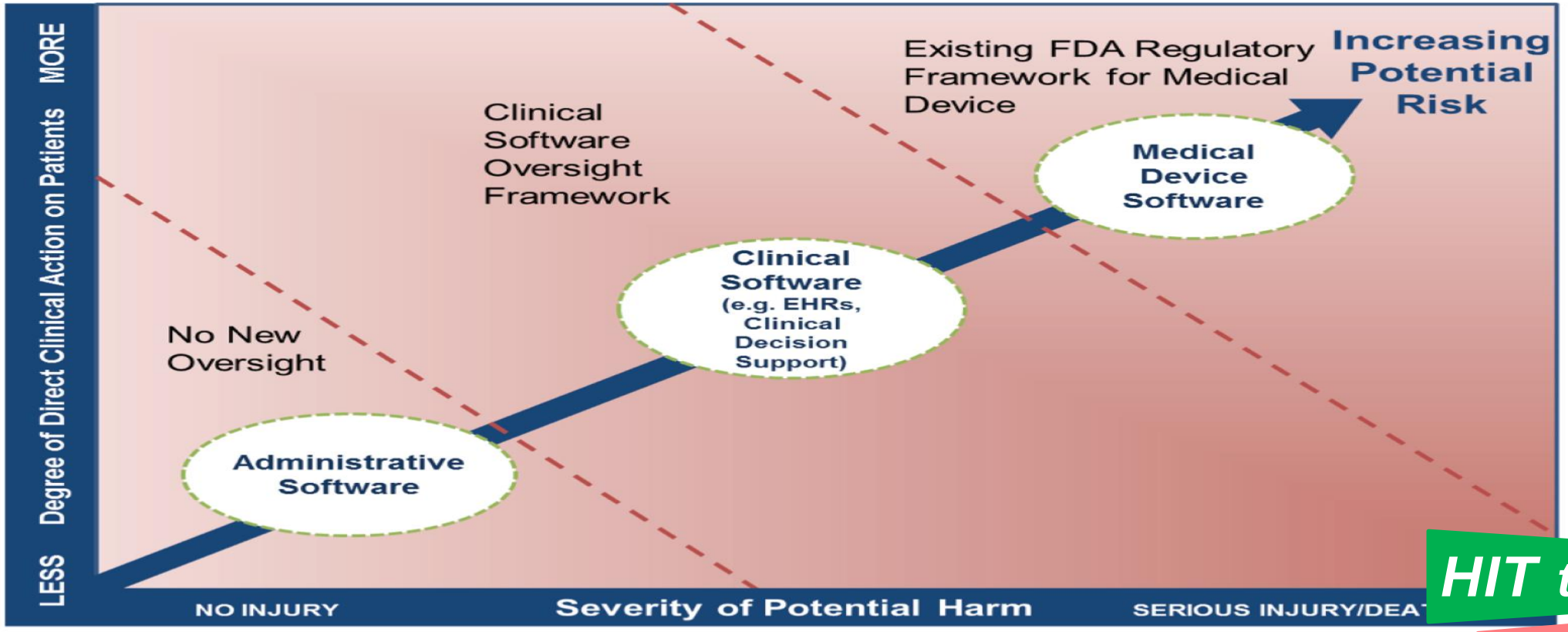


Reference: Bipartisan Policy Center (BPC)(2013). An Oversight Framework for Assuring Patient Safety in Health Information Technology

HIT to Safety

醫療資訊科技(HIT)的風險與監管程度

- FDA對醫療儀器的監管方法通常不適用於醫療資訊科技(HIT)
- 醫療資訊科技的安全風險主因，常跨不同角色(開發人員、導入者和使用者)及系統生命週期(設計、開發、導入、客製、 升級、維護)



Reference: Bipartisan Policy Center (BPC)(2013). An Oversight Framework for Assuring Patient Safety in Health Information Technology

HIT to Safety

FDA對於系統軟體(SaMD)的管理與認證行動

適用於軟體即醫療設備(SaMD)，建議主動接受認證及證明本身的品質文化和組織卓越

病人安全 Patient Safety

足以證明致力於提供病人安全的體驗(safe patient experience)，並關注與強調病人安全是所有決策(decision-making)過程關鍵因素。

產品品質 Product Quality

足以證明提供的SaMD產品具最高品質程度(highest level of quality)，且產品從開發、測試和維護均維持此一承諾。

臨床責任 Responsibility

承諾以負責任方式進行臨床評估(clinical evaluation)，確保以病人為中心的問題(patient-centric issues)得到適當解決(如標籤和人為因素)。

網路安全 Cybersecurity

證明對網路安全承諾(commitment to protect cybersecurity)，並與相關利益者的主動解決網絡安全問題。

積極文化 Proactive Culture

證明對主動(proactive approach)針對軟體產品進行監測、評估用戶需求和持續學習的承諾

HIT to Safety

FDA對於系統軟體(SaMD)與病人安全的推動行動

第3060(b)條，衛生部(HHS) 每兩年發佈一次，提供最新關於與HIT對病患相關的任何健康風險和益處資訊

- **FD&C 法案第520(o)(1)**，提供**非設備軟體功能**對**病患安全影響**調查結果，包括**促進安全**、**教育**和**能力**➔**最佳行動(Best Practices)**
- **2022/12月發佈調查結果**，分析美國2020年至2022年7月31日研究結果及相關文章，提供最新證據**(病患安全影響、健康益處和風險、最佳實踐)**

HIT(非設備軟體功能)相關調查範圍

- 醫療照護機構作業系統
- 診斷、治療、減輕、預防或治療疾病相關系統或設備
- 病患電子病歷系統
- 資訊系統資料傳輸、存儲、轉換格式或顯示
- 臨床試驗或其他設備數據

A. Administrative Support of a Health Care Facility

Software functions included in this category are defined in section 3060(a) as intended:

> *...for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow.*

Impacts to Patient Safety

FDA received three adverse event reports[9] related to laboratory workflow applications. The first error occurred after a software update to a culture workshop test where a revised protocol length was not sent to the intended instrument and was automatically changed [illegible] The second error caused samples to revert to "ready for reading" even after s[illegible] which led to delays in workflow. A third error led to a patient's aspartat[illegible] results to being automatically validated due to a missing flag and was re[illegible] laboratory to the patient.

Changes or additions since last published report: New adverse event types. In[illegible] presented on this software function includes adverse events related to laborato[illegible] were not reported in the 2020 Report.

《21 世紀醫療發展法案》
21st Century Cures Act

HIT to Safety

醫療資訊科技與病人安全風險

Healthcare Information Technology and Patient Safety Risk

ECRI：2022年前十大健康科技危害風險事件警示

01 網路安全與攻擊(Cybersecurity)
02 供應鏈短缺
03 輸液幫浦損壞(Infusion Pumps ➔Medication Errors)
04 緊急儲備物資不足
05 遠距醫療流程與系統性人因因素(Human Factors)
06 未遵循注射幫浦指引流程(Medication Delivery Errors)
07 AI影像重建與辨識的異常(診斷結果的風險)
08 不良的十二指腸鏡再處理流程(汙染) (Duodenoscopy)
09 保護不足一次性防護衣風險(Disposable Gowns)
10 無線網路的中段與死角區(Wi-Fi Dropouts , Dead Zones)

HIT to Safety

Real World Evidence- HIT 病安相關事件統計

■75%的醫療資訊科技相關病安事件可以被預防➔我們可以如何做

- <1%死亡、1%嚴重傷害、4%中度傷害、13%低度傷害、82%無傷害

The effects and preventability of 2627 patient safety incidents related to health information technology failures: a retrospective analysis of 10 years of incident reporting in England and Wales

Guy Martin, Saira Ghafur, Isabella Cingolani, Joshua Symons, Dominic King, Sonal Arora, Ara Darzi

Global Health Innovation, Imperial College London, London, UK (I Cingolani PhD, J Symons); and DeepMind Health, London, UK (D King)

Correspondence to: Dr Guy Martin, National Institutes of Health Research Patient Safety Translational Research Centre, St Mary's Hospital, Imperial College London, London W21NY, UK guy.martin@imperial.ac.uk

Findings We identified 2627 incidents related to health IT failures. 2557 (97%) of 2627 incidents were assessed for harm (70 incidents were excluded). 2106 (82%) of 2557 health IT failures caused no harm to patients, 331 (13%) caused low harm, 102 (4%) caused moderate harm, 14 (1%) caused severe harm, and four (<1%) contributed to the death of a patient. 1964 (75%) of 2627 incidents were deemed to be preventable.

Interpretation Health IT is fundamental to the delivery of high-quality care, yet there is a poor understanding of the effects of IT failures on patient safety and whether they can be prevented. Failures are complex and involve interlinked aspects of technology, people, and the environment. Health IT failures are undoubtedly a potential source of substantial harm, but they are likely to be under-reported. Worryingly, three-quarters of IT failures are potentially preventable. There is a need to see health IT as a fundamental tenet of patient safety, develop better methods for capturing the effects of IT failures on patients, and adopt simple measures to reduce their probability and mitigate their risk.

HIT to Safety

Reference: ***Lancet Digit Health***. 2019 Jul;1(3):e127-e135

Real World Evidence- HIT 病安相關事件案例

■閉環式(closed loop)系統模式➔即時有效治療與減少診斷錯誤

- 資訊系統開發和應用 ，應在正確時間以正確格式將正確信息傳達給正確的人

England and Wales : 真實病安事件案例警示

Death
"Patient became acutely unwell overnight, had been seen by on call team during the previous day… Found to be in **probable urinary sepsis**. Later died. **[Results]** system not working properly and so **positive MSU [mid-stream urine] from 4/7 [4 days] earlier had been missed by ward team and on call team**"
Severe harm
"Main server for pharmacy IT system failed. **No 24 h maintenance contracted for from server provider. No 24 h internal IT cover**. **[Result]** is **complete failure of pharmacy operational system"**
Moderate harm
"[…] system error resulted in approximately **1700 patient records having missing data items on attached specimen records**. This caused multiple specimens to be inaccessible"

HIT to Safety

Reference: ***Lancet Digit Health***. 2019 Jul;1(3):e127-e135

Real World Evidence-以類型看HIT病安相關事件

■National Reporting and Learning System(England and Wales):

2004~2016 通報 **13,748,411** 件病安事件 ➔ **其中 2,627件 屬醫療資訊科技相關事件**

①27.4% 基礎設施Infrastructure (醫療人員、機構設施與環境所造成)

- IT or telecommunications failure or overload
- Absence of suitably trained or skilled staff
- Failure or delay in collection or delivery systems

②16.7% 臨床診斷作業(檢查診斷、檢驗、評估)

- Failure, delays in receiving incorrect or missing test results or reports
- Delays or failure of diagnosis or tests
- Inadequate, incomplete, or missing scans, x-rays, or sample specimens

③14.0% 文件與紀錄(電子和紙本記錄、身份辨識和藥物記錄)

- Missing, inadequate, or wrong documentation, or no access or delays in obtaining documentation
- Incorrectly identified patients

④9.9% 醫療設施或設備

- Failure of devices or equipment

⑤6.5% 給藥錯誤

⑥5.9% 治療或處置過程

- Delay or failure of the treatment or procedure or the inappropriate or wrong treatment or procedure

⑦5.8% 病患接收、傳送、出院 (病患不明離院)

- Delays or failure in transport, transfer, or patient discharge

⑧5.5% 臨床作業中的同意、溝通和保密

- Communication failure

醫療資訊系統 / 人員/ 作業流程 ➔ 失效

- Failure Overload
- Delay Missing Wrong
- Inadequate Incomplete Incorrect

Reference: ***Lancet Digit Health***. 2019 Jul;1(3):e127-e135

Safety

醫療資訊科技-管理策略與安全認證

Healthcare Information Technology- Management Strategy and Safety Certification

建立HIT與病患安全性的治理架構與策略方法

■資訊科技可降低醫療疏失、提高照護效率、降低成本、改善品質

●**避免不良的健康結果**：減少HIT開發過程的缺點，如設計、開發、導入(implementation)、客製化(customization)、系統整合(integration)與使用

Health IT 與病患安全管理策略

品質管理理論的運用
Promote the Use of Quality Management Principles

■安全的HIT，從系統生命週期(設計、開發、導入、客制與使用)，**需要參考品質系統方法**。

■從品質管理原則，確定安全的HIT必要**符合的基本要素**

選用、開發與採用最佳的標準與指引
Identify , Develop, and Adopt Standards and Best Practices

■**參考最佳的標準與指引**，提供的高品質的HIT 產品和系統服務

- ●系統的可用性(usability)
- ●操作互動性 (Interoperability)
- ●系統導入、客製與維護
- ●風險管理

採用評估安全性的合規工具
Leverage Conformity Assessment Tools

■確保HIT 產品、服務、系統、開發商、供應商，**符合要求標準或指定要求，符合病人安全目標**

- ● 產品測試、認證、認可
- ● 驗證系統操作互動性測試(選定功能開發標準)
- ● **政府或獨立機構如何執行**

建立持續學習與改善的環境
Create an Environment of Learning and Continual Improvement

■公私合營發展**安全、透明、學習、持續改進文化**

■從供應商、開發商、醫療提供者，**建立HIT相關安全問題的報告與分析。**

■學習系統的治理結構和功能避免重複監管

HIT to Safety

Reference: FDA(2014).FDASIA Health IT Report : Proposed Strategy and Recommendations for a Risk-Based Framework

HIT開發標準與指引-避免病人安全風險

- **The ISO/IEC 25010 standard defines a software product quality model , and it allows Health IT developers that can affect patient safety**

Characteristics	Sub-characteristics	Risk
1.功能合適性 Functional Suitability	1.1 完整功能(completeness)	**R1** - Lack of functionalities that support clinical workflow **R2** - Lack of coding, standardization, and structuring data **R3** - Lack of features to detect duplicate patient records
	1.2 正確功能(correctness)	**R4** - Inaccurate, outdated, or incomplete decision support rules **R5** - Software bugs
	1.3 合適性(Appropriateness)	**R6** - Inadequate content import features **R7** - Pre-populated fields **R8** - Inadequate alerting **R9** - Allow tasks to be performed simultaneously
2.可用性 Usability	2.1 辨識性(Appropriateness recognizability)	**R10** - Inadequate display of information
	2.2 易學性(Learnability)	**R11** - Difficulty in understanding current status of user actions
	2.3 可操作性(Operability)	**R12** - Difficulty in interacting with EHR
	2.4 防呆機制(User error protection)	**R13** - Interface prone to user error
	2.5 使用介面設計(User interface aesthetics)	-
	2.6 可近性(Accessibility)	-

ISO/IEC 25010
STANDARD

HIT to Safety

Reference: Identification of Patient Safety Risks Associated with Electronic Health Records: A Software Quality Perspective. ***Stud Health Technol Inform*** (2015).216:55-9

HIT開發標準與指引-避免病人安全風險

- The ISO/IEC 25010 standard defines a software product quality model , and it allows Health IT developers that can affect patient safety

Characteristics	Sub-characteristics	Risk
3.效能效率 Performance Efficiency	系統反應時間 (Time behavior)	R14 - Delay in system response
	系統資源耗用 (Resource utilization)	-
	系統容量 (Capacity)	-
4.相容性 Compatibility	跨系統共存性 (Co-existence)	-
	跨系統間的可操作性 (Interoperability)	R15 - Communication errors between systems
5.可靠性 Reliability	系統可用性 (Availability)	R16 - EHR unavailability
	系統成熟度/容錯能力/可恢復性 Maturity/Fault tolerance/Recoverability	
6.安全性 Security	系統機密性/完整性/不可否認性 Confidentiality/Integrity/Non-repudiation	-
7.維護 Maintainability	系統模塊化/可重用性/可修改性/可測試性 Modularity/Reusability/Modifiability/Testability	
8.可轉移性 Portability	系統適應性/可安裝性/可更換性 Adaptability/ Installability /Replaceability	

ISO/IEC 25010 STANDARD

HIT to Safety

Reference: Identification of Patient Safety Risks Associated with Electronic Health Records: A Software Quality Perspective. ***Stud Health Technol Inform*** (2015).216:55-9

資訊系統或軟體安全性評估-ONC的方法與認證標準

Health IT 認證標準(Certification Criteria)

- 2015年版HIT認證標準共**有八個類別58項**。**ONC授權認證機構(ONC-ACB)**對經授權測試實驗室(ONC-ATL)**符合認證標準的HIT產品進行認證**，並這些產品將列在認證的**HIT產品清單(CHPL)** 中，以確定產品包含**正確的認證功能在醫療環境與病患照護中實踐**。

The Office of the National Coordinator for Health Information Technology

Interoperability is essential for systems to communicate

ONC Certified HIT

Certification supports clinician engagement in clinical practice Improvement and care coordination activities using health IT – including participation in CMS programs

Patients can access and send their health information electronically

Clinicians & Hospitals have tools for clinical processes, care coordination, and quality improvement

Developers can assure their customers that their product meets recognized standards and functionality

Reference: https://www.healthit.gov/topic/certification-ehrs/2015-edition

The ONC 2015 Edition 認證標準(Certification Criteria)

1.臨床過程
Clinical Processes

醫囑-藥物
CPOE – Medications

- 提供醫生以**電子方式開立醫囑**傳輸給接收者(藥局)。
- 認證分三個類別，**藥物**、**實驗室**和**影像醫學科**。
- 利用醫囑(**CPOE**)開立藥物，**減少藥物品項相關錯誤**，並可執行自動 **藥物-藥物**及 **藥物-過敏**的交互作用檢查。在患者的病歷中得到更新藥物資訊

3.臨床品質測量
Quality Measurement

輸入與計算
Import and Calculate

- **臨床品質測量(CQM)**協助臨床醫生**了解與改善醫療照護品質**。 CMS也使用CQM品質改進、發佈報告
- 透過**輸入標準化格式CQM數據**，支持簡化醫生流程與輸入患者數據。
- IT系統可以**使用標準化格式正確計算eCQM結果。**

7.資訊系統設計與效能
IT Design and Performance

安全強化設計
Safety-Enhanced Design

- 認證標準強**關注HIT的可用性和安全性**。HIT 需經過的功能認證，證明**符合特定的使用者為中心設計需求**。
- 驗證HIT能力作為**預防錯誤**和**提高病患安全**。

7.資訊系統設計與效能
IT Design and Performance

品質管理系統
Quality Management System

- 認證標準要求HIT開發人員使用**品質管理系統(QMS)**，確保系統功能在**開發**、**測試**、**實施**和**維護**中符合認證。
- HIT開發人員使用的**品質管理系統(QMS)**，必須與聯邦QMS標準或標準制定組織(ISO)製定的QMS標準一致。

Reference: https://www.healthit.gov/topic/certification-ehrs/2015-edition

The ONC 2015 Edition Update: 2022 Requirements

■Real World Testing 2023 Plans

- 在**2024年**發佈**符合ONC-ACB 認證標準的Health IT系統CHPL品項**，必須在**2022年12月15日**前提出**真實世界測試計劃(Testing Plans)**。
  - ➢通過真實世界測試，表示開發Health IT的產品可在真實世界的**環境(settings)**和**情景(scenarios)**操作，**符合要求的操作性和功能性**；操作性(interoperability)和數據交換(data exchange)測試數據，**驗證Health IT是否如預期執行**，**驗證結果以公開方式描述與報告**。

真實世界測試成功意涵

- ›**系統符合認證標準：技術標準(technical standards)**和**詞彙代碼集(vocabulary code)**
- ›在真實醫療照護環境中進行電子健康資訊(EHI)交換，**並銷售給使用者使用**
- ›在驗證Health IT產品中，執行電子健康資訊(EHI) **接收和使用**

Reference: ONC Health IT Certification Program Developer Roundtable (November 15, 2022)

The ONC Certified HIT Product List (CHPL)

Certified HealthIT | PRODUCT LIST

Search CHPL | CMS ID Creator | Compare Products | CHPL Resources | Shortcuts

ADMINISTRATOR LOGIN

Search by Developer, Product, or ONC-ACB/CHPL ID | Browse all

- API Info for 2015 Ed. Products
- SED Info for 2015 Ed. Products
- Products: Corrective Action
- Decertified Products
- Real World Testing
- Inactive Certificates
- Banned Developers
- Charts

Certified HealthIT | PRODUCT LIST

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Apervita Platform

CHPL Product Number: 15.99.04.3074.Aper.20.00.0.200629

ONC-ACB Certification ID: 15.04.04.3074.Aper.20.00.0.200629

Certification Date: Jun 29, 2020 | Last modified Date: Dec 1, 2021

+Cert ID | +Compare

Developer

Apervita Inc.

https://www.apervita.com

Self-developer: No

SEE ALL CERTIFICATION CRITERIA / CLINICAL QUALITY MEASURES

Certification Criteria (7 met)

- 170.315 (c)(3): Clinical Quality Measures - Report — View details
- 170.315 (d)(1): Authentication, Access Control, Authorization — View details
- 170.315 (d)(2): Auditable Events and Tamper-Resistance — View details
- 170.315 (d)(3): Audit Report(s) — View details
- 170.315 (d)(5): Automatic Access Time-out — View details
- 170.315 (g)(4): Quality Management System

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產品資訊

Search CHPL | CMS ID Creator | Compare Products | CHPL Resources | Shortcuts

FILTERS APPLIED Certification Edition: 2015, 2015 Cures Update | Certification Status: Active, Suspended by ONC, Suspended by ONC-ACB

ONC-ACB: Drummond Group, ICSA Labs, Leidos, SLI Compliance | Real World Testing: ANY | Has RWT Plans URL, Has RWT Results URL

SEARCH RESULTS: (1-25 of 647 Results)

DOWNLOAD 25 RESULTS

CHPL ID	Certification Edition	Developer	Product	Version	Certification Status	Real World Testing Plans URL	Real World Testing Results URL
15.05.05.3121.ONEL.01.00.1.220823	2015 Cures Update	1Life Healthcare, Inc	1Life	1.0	Active	https://apidocs.onemedical.io/legal/real_world_test_plan/	N/A
15.05.05.3121.CHRP.01.01.1.220912	2015 Cures Update	1Life Healthcare, Inc	Chirp	1.0	Active	https://apidocs.chirp.app/#real_world_test_plans	N/A
15.02.05.1026.ASPM.01.01.0.220203	2015	ASP.MD Inc.	ASP.MD Medical Office System	92	Active	https://www.asp.md/real-world-test-plan/	N/A
		ASPYRA, LLC	CyberLAB	7.3.1	Active	https://aspyra.com/wp-content/uploads/2021/12/ASPYRA_Real_World_Test_Plan_CY2022_15Oct2021-Signed-GB.pdf	N/A
			Crystal Practice				

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測試報告

Reference: https://chpl.healthit.gov/#/search

醫療資訊科技-病安事件之通報系統

Reporting system of Healthcare Information Technology for Patient Safety Incident

HIT病安相關事件通報-澳洲健康安全與品質委員會

■醫療軟體安全性事件的數據與報告架構分類(ISO/TS 20405:2018)

- 多個政府機構和病患安全組織(*US Joint Commission , American Nursing Informatics Association , Emergency Care Research Institute (ECRI)*)，採用作為病安事件調查分類依據
- 2019年國際標準化組織(ISO)採用新技術規範，作為改善醫療軟體安全性報告形式

1.可用性與基礎架構 Availability and infrastructure

- 1.1 Workstation not available
- 1.2 Workstation down/slow
- 1.3 Printer/scanner down/slow
- 1.4 Network down incl. CIS slow
- 1.5 CIS not available/ licensed
- 1.6 CIS not accessible (e.g. login issues)
- 1.7 Power failure
- 1.8 Computer security, virus
- 1.9 Data storage and backup

2.醫療資訊系統的使用 Using CIS

- 2.1 Permissions, information governance
- 2.2 **Unfamiliarity/ training**
- 2.3 **Use error; wrong entry/retrieval**
- 2.4 **Cognitive load**
- 2.5 Unauthorized access

實際案例

- 使用者訓練不足不熟悉
- 列印錯誤的病歷文件
- 過多複雜的操作環境

3.醫療資訊系統功能 Problems with CIS

- 3.1 **Wrong output/ display error**
- 3.2 **CIS functionality (usability, user interface, task fit)**
- 3.3 CIS Integration with workflow (collaborative task)
- 3.4 Local CIS configuration (DSS alerts, rules, etc.) and changes
- 3.5 **Device interface (smart pumps)**
- 3.6 **Interface with another CIS**

4.醫療資訊系統的轉換 Transitions

- 4.1 Hybrid record system
- 4.2 **Record migration**
- 4.3 **Software updates**
- 4.4 **Downtime procedures** (transition to paper and back to EMM)

實際案例

- 新舊系統轉換(Migration)
- 例行系統升級
- 系統停機期間

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

HIT to Safety

Reference: (1) Australian Commission on Safety and Quality in Health Care(2019). A health IT-related classification system
(2)https://www.iso.org/obp/ui/#iso:std:iso:ts:20405:ed-1:v1:en

HIT病安相關事件通報-外部獨立組織的角色與功能

病安事件通報系統
Patient safety event reports

■ **收集事件與改善醫療資訊系統(Health IT)**

- **建立全國性HIT資料庫**：監測與分析資訊相關系統可用性(usability) 與安全性(safety)
- **病安風險和危害辨識**：病患安全事件報告分析。
- **獨立組織的專業協助**：協助醫療機構進行調查和分析，解決與改善意外傷害(Unintended harms)
- **建立系統的開發與設計標準**
- **建立結果測量方法**：監測與分析資訊相關系統可用性(usability) 與安全性(safety)
- **發佈警示與報告(Alert & Report)** ：醫療資訊系統(科技)相關風險報告與學習工具

Events reported to FDA "Electronic Health Record"

FDA FAERS FDA Adverse Event Reporting System

年度	Event Type				
	Death	Injury	Malfunction	Other	TOTAL
2010		1			1
2011		2			2
2012			59		59
2013	1	10	17		28
2014		5	32		37
2015	2	5	35		42
2016	1	7	20	1	29
2017		5	65		70
2018	5	6	74		85
2019	6	2	40		48
2020		1	23		24
2021	1		15		16
2022		1			1
TOTAL	***16***	***45***	***380***	***1***	***442***
	3.6%	***10.2%***	***86.0%***	***0.2%***	***100.0%***

HIT to Safety

Reference: A Decade of Health Information Technology Usability Challenges and the Path Forward. ***JAMA(2019) .26;321(8):743-744.***

Data queried from the FDA MAUDE Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm

Real World Evidence：HIT病安相關事件通報現況

■ 未通報 HIT 病安相關事件

- 通報太難或花費太多時間(OR=0.81)
- 自覺不需要通報報告(OR=0.67)
- 對組織的流程沒有影響(OR=0.63)
- 擔心後果(OR=0.61)

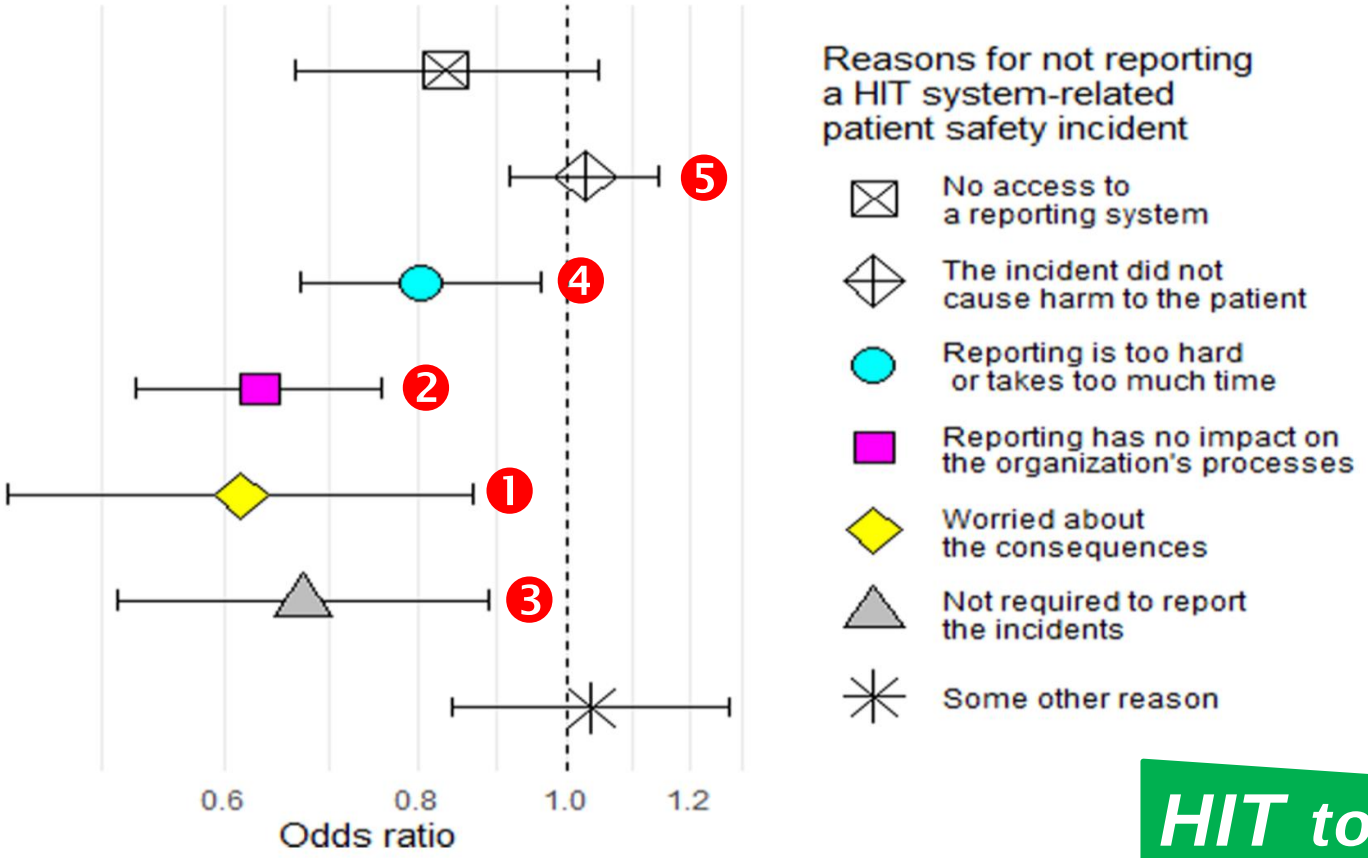
■ 鼓勵與提高HIT事件通報

- 公平鼓勵與對待通報者
- 對通報者表達意見鼓勵及無偏見
- 即使沒有對病人傷害也應通報

■ HIT事件通報系統與作業

- 易於通報者使用
- 易於辨識不同類型的事件問題
- 事件報告應提供相關人，例如系統嚴格測試與預防系統錯誤

Cross-sectional survey data were collected in 2017 from working-aged registered nurses in Finland.(1399 nurses)



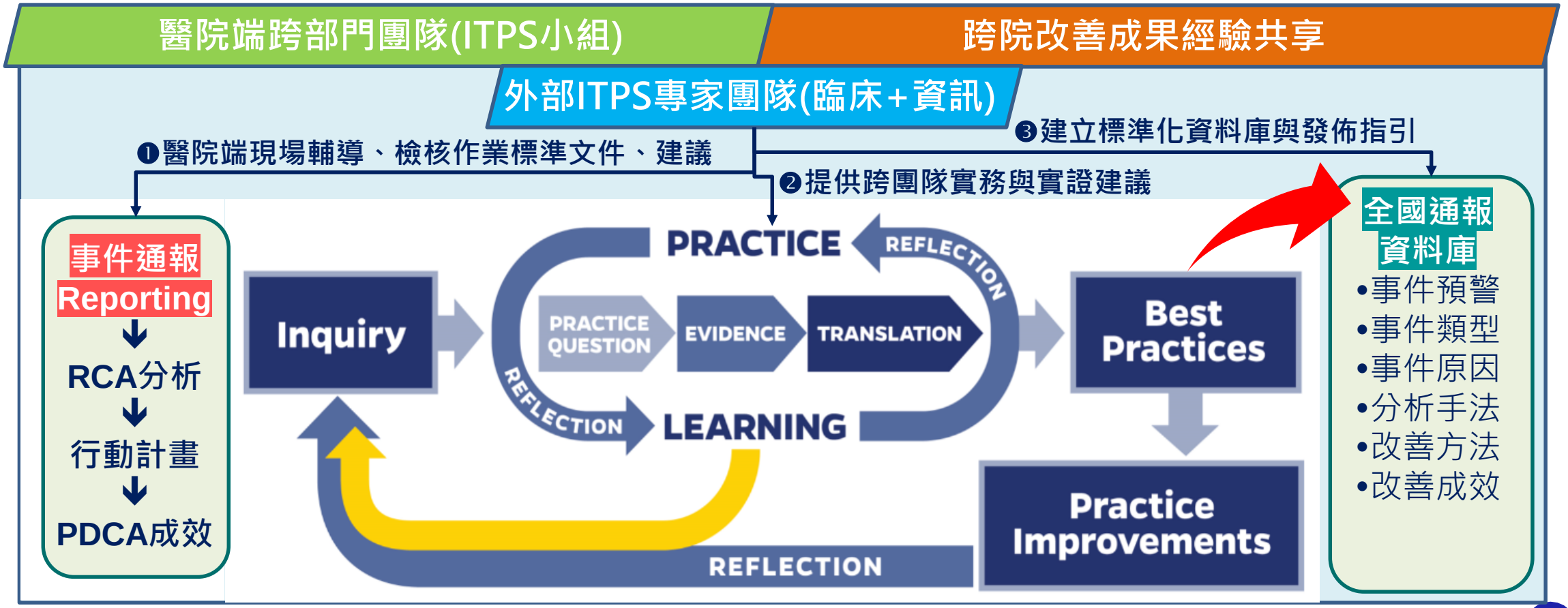
HIT to Safety

Reference : Reporting of health information technology system-related patient safety incidents: The effects of organizational justice. ***Safety Science***. 2021 .144

台灣版ITPS:提供內部與外部持續學習與改善的環境

■ Johns Hopkins Evidence-Based Practice Model

- **Problem-solving approach** to clinical decision-making and is accompanied by user-friendly tools to guide group use. The model and tools enhance team collaboration and care coordination.



Reference : https://www.hopkinsmedicine.org/evidence-based-practice/ijhn_2017_ebp.html

醫療資訊科技-醫院評鑑相關規法

Healthcare Information Technology - Regulations Related to Hospital Accreditation

持續確保HIT安全性-結合外部評鑑規範

■ The Pew Charitable Trusts and MedStar Health- Safe Use of Digital Systems

➢ **Ten Best Practice**: Clinical Decision Support(3), Order sets, Governance, Training, ***Hazard identification***, Hazard reporting, Hazard analysis and resolution, Health IT awareness

目的	案例	醫院評鑑等級類別及要求		
		基本Basic	中階Intermediate	高階Advanced
主動辨識(Identifying)醫療資訊技術可能造成病患傷害的風險問題，並持續致力於減少傷害與持續改善HIT系統。 平常有**作業程序來識別HIT危害(Hazards)**，並且頻繁地測試與HER有關錯誤。	醫院可使用**自我評估工具**，並有定期對HIT系統進行**安全性評估**。	■ 醫院有**作業程序**，來辨識與HIT相關的安全風險問題。	■ 醫院依**實證理論**或**已建立多項作業程序**，來辨識與HIT相關的安全風險問題。 ■ 醫院的安全辨識作業程序，留有**評估方法**或**評估結果的文件**	■ 醫院依實證理論或已建立多項作業程序(process)，來辨識與HIT相關的安全風險問題，**並且已辨識風險如何地被追蹤(tracked)**。 ■ 醫院的安全辨識作業程序，留有評估方法或評估結果的文件 ■ 醫院可列舉HIT相關的安全風險如何的追蹤，**且如何改善降低風險**

HIT to Safety

MedStar Health National Center for Human Factors in Healthcare

THE PEW CHARITABLE TRUSTS

Reference: The Pew Charitable Trusts and MedStar Health (2020). Hospitals Can Take Key Steps to Improve Safe Use of Digital Systems

持續確保HIT安全性-結合外部評鑑規範

- **The Pew Charitable Trusts and MedStar Health- Safe Use of Digital Systems**
  - **Ten Best Practice**: Clinical Decision Support(3), Order sets, Governance, Training, Hazard identification, ***Hazard reporting***, Hazard analysis and resolution, Health IT awareness

目的	案例	醫院評鑑等級類別及要求		
		基本Basic	中階Intermediate	高階Advanced
事件報告(Hazard reporting)是記錄和分享資訊的過程 員工應該有一個**作業程序**，來通報他們可能遇到的HIT危害事件 所有員工都應該**知道如何提出事件報告**	醫院有**病患安全事件通報系統**，該系統具有可**記錄與分析**事件報的與HIT危害相關內容。	■醫院具有提供人員，**提出與HIT相關安全風險通報的方法或系統**。	■醫院具提供人員，提出與HIT相關安全風險通報的**方法、流程與系統** ■通報過程包括**事件報告資訊系統**或**已列印存檔的報告**。	■所有員工應該能夠回覆，如何的通報或填寫HIT危害事件報告內容

MedStar Health National Center for Human Factors in Healthcare

THE PEW CHARITABLE TRUSTS

Reference: The Pew Charitable Trusts and MedStar Health (2020). Hospitals Can Take Key Steps to Improve Safe Use of Digital Systems

HIT to Safety

Execs Accelerate Health IT Innovation, Digital Health Transformation

➔ "Benefits" vs. "Risk or Harm"

Thanks Your Attention

HIT to Safety